FEB 1 4 2001

K010246

510(k) Summary of Safety and Effectiveness
KyphX™ Inflatable Bone Tamp

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 and 21 CFR §807.92.

General Information

Manufacturer:	Kyphon Inc. 1350 Bordeaux Dr. Sunnyvale, CA 94089
Contact Person:	Karen Talmadge, Ph.D. Executive Vice President
Date Prepared:	25 January 2001

Device Information

Classification:	Class II
Trade Name:	KyphX™ Inflatable Bone Tamp
Common Name:	Tamp

Device Description

The KyphX™ Inflatable Bone Tamp is a bone tamp with an inflatable component at the distal end.

Intended Use

KyphX™ Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

Sterilization

The KyphX™ Inflatable Bone Tamp is sterilized using gamma radiation and meets the requirements of ANSI/AAMI/ISO11137:1994 for gamma-sterilized devices.

Mechanical Tests

Mechanical testing of the KyphX™ Inflatable Bone Tamp verifies the device meets the performance specifications of K981251 Inflatable Bone Tamps.

Biocompatibility Evaluations

The materials used in the construction of the KyphX™ Inflatable Bone Tamp meet the requirements for "Externally Communicating Devices, Tissue/Dentin/Bone, Limited Contact" described in the FDA Blue Book Memorandum #G95-1, "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The biocompatibility tests demonstrate that this device is biocompatible.

Substantial Equivalence[1]

The KyphX™ Inflatable Bone Tamp is substantially equivalent to the currently marketed Kyphon Inflatable Bone Tamp (K981251).

Summary

The predicate, clinical and mechanical testing information incorporated from K981251 by reference into this submission clarify that the specific anatomic sites of spine, hand, tibia, radius and calcaneus are intended uses in K981251 and can be added to the product labeling. The KyphX™ Inflatable Bone Tamps meet the physical and performance specifications of the K981251 Kyphon Inflatable Bone Tamps. Manufacturing changes are non-significant, and do not alter the safety or effectiveness of these devices when compared to the devices of K981251.

Karen Talmadge, Ph.D.
Executive Vice President, Kyphon Inc.
25 January 2001

[1] As with Kyphon's cleared Inflatable Bone Tamp 510(k), K981251, any statement regarding "substantial equivalence' made in this submission only relates to whether the product can be lawfully marketed without premarket approval or reclassification, and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. The present submission is therefore not related to the coverage of any patent or whether these products or their uses may be considered distinct from a patent point of view.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Karen Talmadge, Ph.D.
Executive Vice President and Co-Founder
Kyphon Inc.
1350 Bordeaux Drive
Sunnyvale, California 94089

Re: K010246
Trade Name: KyphX™ Inflatable Bone Tamp
Regulatory Class: II
Product Code: HRX and HXG
Dated: January 25, 2001
Received: January 26, 2001

Dear Dr. Talmadge:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010246

Device Name: KyphX™ Inflatable Bone Tamp

Indications For Use:

KyphX™ Inflatable Bone Tamps are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine, hand, tibia, radius and calcaneus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)
Division of General Restorative
and Neurological Devices

510(k) Number K010246

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)